net 2 1 2002 88

PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/251.133 INFORMATION DISCLOSURE Filing Date 02/16/1999 STATEMENT BY APPLICANT Girish V. Shah First Named Inventor 2002 Art Unit 1642 (use as many sheets as necessary) C. Yaen **Examiner Name** <u>TECH CENTE</u>R 1600/2900 1 of Attorney Docket Number Sheet 01819232

	***		U.S. PATI	ENT DOCUMENTS	
Examiner Initials*		Document Number Number-Kind Code ² (if known,	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CY	1	US- 4826813		Huffman, et al	
CY	2	US- 4876243	10/24/1989	Marshall, et al.	
CY	3	US- 6251613 B1	06/26/2001	Kishimoto, et al.	
	<u> </u>	US-			
	<u> </u>	US-			
		US-	·		
		US-			
	<u> </u>	US-			
	L	US-			
		US-			
		US-			
	<u> </u>	US-			
		US-			
		US-			

		FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code 3 -Number -Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	-	-				
						Ш

Examiner Signature	Chous	Uph HY2	Date Considered	1-21-03
Signature	2 /000	ganie	Considered	_

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Sheet

PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Control of the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449b/P10
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

2

(use as many sheets as necessary)

of

5 o

Co	mplete if Known		ì
Application Number	09/251.133	BEC	EIVED
Filing Date	02/16/1999	ILU	FIVED
First Named Inventor	Girish V. Shah		_
Group Art Unit	1642	OCT 2	5 2002
Examiner Name	C. Yaen		
Attorney Docket Number	04040222		

TECH CENTER 1600/29

		ILUTIU	
		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CY	4	LAZAR, ET AL., Transforming growth factor alpha: Mutation of aspartic acid 47 and leccine 48 results in different biological activities.," Molecular and Cellular Biology, 8 (1), p. 1247-1252,1988	
CY	5	BURGESS, ET AL., Possible Dissociation of the heparin-binding and mitogenic activities of heparin-binding (acidic fibroblast) growth facto-1 from its receptor-binding activites by site-directed mutagenesis of a single lysine residue, J. Cell Biology, 111: p. 2129-2138,1990.	·
cY	6	Acession No. P55062, Database SwissProt, Talter, L. et al. Mamm. Genone 5: 216-221, 1994.	
CΥ	7	Acession No. H86387, Database PIR, 03/2001.	
cγ	8	Acession No. AAB48241, database Geneseq, In U.S. Patent 6160202, 12/2000.	
cy	9	Acession No. Q9MS96, Database SPTREMBL, Whitney, S.M. 10/2000.	
CΥ	10_	CUSSENOT, ET AL., "Evaluation and clinical valure of neuroendocrine differentiation in human prostatic tumors," The Prostate Supplement, p. 43-51,1998.	
cγ	11	COHEN, ET AL., "Neuroendocrine differentiation in prostatic adenocarcinoma and its relationship to tumor progression," CANCER, p. 1899-1903, 1994.	
CΥ	12	HUANG ET AL., "Relation between neuroendocrine expression of prostatic carcinoma an prognosis," CHUNG. HUA. I. HSUEH. TSA. CHIH, Vol. 74 (No. 62), p. 23-25, 1994.	
сч	13_	KADMON ET AL., "Elevated Plasma chromogranin-a concentrations in prostatic carcinoma," J. Urol., p. 358-61, 1991.	
CY	14	SCHUMACHER ET AL., "Identification of d-peptide ligands through mirror-image phage display," Science, p. 1854, 1996.	

Examiner Signature Chrysh h Date Consider

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/08B (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number &

Attorney Docket Number

Shancy Complete if Known **Application Number** 09/251.133 02/16/1999 Filing Date First Named Inventor 1642 Yaen Group Art Unit **Examiner Name**

01819232

RADEMAP. Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet of

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
cy	15	APOSTOLOPOULOS, ET AL., "MUC1 cross-reactive gal alpha (1,2) gal antibodies in humans swithc immune responses from cellular to humoral," Nature Medicine, Vol. 4 (No. 3), p. 315-320, 1998.	
cy	16	SAMUEL, ET AL., "Immunogenicity and antitumor activity of a liposomal MUC1 peptide-based vaccine," Int. J. Cancer, p. 295-302, 1998.	
cy	17	FOON, ET AL., "Clinical and immune responses in advanced colorectal cancer patients treated with anti-idiotype monoclonal antibody vaccine that mimics the carcinoembryonic antigen," Clinical Cancer Research, p. 1267-1276, 1997.	
сү		COLE, ET AL., "Characterization of a sustained-release delivery system for combined cytokine/peptide vaccination using a poly-N-acetyl glucosamine-based polymer matrix," Clincal Cancer Research, p. 867-873, 1997.	
Çγ	19	ZHANG, ET AL., "Expression of potential targe antigens for immunotherapy on primary and metastatic porstate cancers," Clincal Cancer Research, p. 295-302, 1998.	
CY	20_	KONO ET AL., "Identification of her2/neu-derived peptide epitopes recognized by gastric cancer-specific cytotoxic T lymphocytes," Int. J. Cancer, p. 202-208, 1998.	
CY	21_	Prions met Aptamers, www.cyber-dyne.com/-tom/aptamer.html.	
CY	22	DNA-based vaccine used to fight cancer, www.newswise.com/articels/CANCER.UIC.HTML	
сy	23	MANGOO-KARIM, ET AL., "Renal epithelial cyst formation and enlargement in vitro: dependenc on cAMP," Proc. Natl. Acad. Sci. USA, p. 6007-6011, 1989.	
٤ ٧		COWLEY, ET AL., "Elevated c-myc protooncogene expression in autosomal recessive polycystic kidney disease," Pro. Natl. Acad. Sci. USA, p. 8394-98, 1987.	
сY	25	GRANTHAM ET AL., "Cyst formation and frowth in autosomal dominant polycystic kidney disease", Kidney Int., p. 1145-1152, 1987.	

Examiner Chrus Lph HK	Date Considered	1-21-03
-----------------------	--------------------	---------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

Sheet

NFORMATION DISCLOSURE TATEMENT BY APPLICANT

(use as many sheets as necessary)

THE STATE OF THE S Complete if Known 09/251.133 Application Number 02/16/1999 Filing Date Girsish -V. First Named Inventor Group Art Unit 1642 **Examiner Name** C. Yaen Attorney Docket Number 01819232

"				
			OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
	Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	cγ	26	CARONE ET AL., "Basement membrane antigens in renal polycystic disease," Am. J. Pathol.," p. 466-471, 1988.	
	CY	27_	GRANTHAM ET AL., "Chemical modification of cell proliferation and fluid secretion in renal cysts," Kidney Int., p. 1379-1389, 1989.	
ĺ	ey	28	DAVIDOW ET AL., "The cystic fibrosis transmemebrane conductance regulatro mediates transepithelial fluid secretion by human autosomal dominant polycystic kidney disease epithlium in vitro," Kidney Int., Vol. 50 (No. 1), p. 208-218, 1996.	
	CY	29	YAMAGUCHI ET AL., "Renal accumulation and excretion of cyclic adenosine monophosphate in a murine model of slowly porgressive polycystic kidney disease," Am. J. Kidney Dis., Vol. 30 (No. 5), p. 703-709, 1997.	,
	CY	30	CARMICHAL ET AL., "Molecular biology of vasopressin receptors," Sem. in Nephrology, Vol. 14 (No. 4), p. 341-48, 1994.	
	و٧	31	FUSHIMI, SASAKI, ET AL., "Cloning and expression of apical membrane water channel of rat kidney collecting tubule," Nature, p. 549-552, 1993.	
	CY	32	YAMAMURA ET AL., "Characterization of a Novel Aquaretic agen, OPC-31260, as an orall effective, nonpeptide vasopressin V2 receptor antagonist," British J. Pharm., p. 787-791, 1992.	
	CY	33	LASZLO, ET AL., "Pharmacology and clinical Perspectives of Vasopressin Antagonists", Pharmacol Rev., p. 73-108, 1991.	
	СУ	34	MAH, ET AL., "Antagonists of arginine-casopressin: experimental and clinical applications," Drugs Future, p. 1055-1070, 1987.	
	CY	35	MANNING ET AL., "Discovery, development, and some uses of vasopressin and oxytocin antagonists," J. Lab. Clin. Med., p. 617-632, 1989.	
	СЧ	36	SORENSEN, ET AL., "Syndrome of inappropriate secretion of antidiuretic hormone (SIADH) in malignant disease," J. Int. Med., p. 97-110, 1995.	

Examiner Chans when X	Date 2-21-03
-----------------------	--------------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Selection Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

CKINKS COS Complete if Known Substitute for form 1449B/PTO 09/251.133 Application Number INFORMATION DISCLOSURE 02/16/1999 Filing Date First Named Inventor STATEMENT BY APPLICANT Girish V Group Art Unit Yaen (use as many sheets as necessary) **Examiner Name** of Attorney Docket Number 01819232 Sheet

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	tnclude name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ
CY	37	SERRADEIL-LE GAL, ET AL., "Characteriztion of SR121463A, a highly potent and selective, orally active vasopressin 2 receptor antagonist," J. Clin. Invest., Vol. 98 (No. 12), p. 2729-2738, 1992.	
eγ	38	SHIMIAU K., "Aquaretic effects of the nonpeptide V2 antagonist OPC-31260 in hydrpenic humans," Kidney International, p. 220-226, 1995.	
د کړ	39	NING, ET AL., "Forskolin stimulates camp production by stimulating vasopressin V2 receptors," J. Am. Soc. Neph, p. 23, 1997.	
cY	40	SCHWARTZ ET AL., J. Clin. Invest. 90, 1275, 1992.	
CY	41	DI SANT'AGNESSE ET AL.,, "Neuroendocrine differentiation in prostatic malignancy," Cancer, ed., Vol. 78 (No. 2), p. 357-361, 1996.	
cY	42_	ZHAU ET AL.,, "Biomarkers associated with prostate cancer porgression," Journal of Celluair Biochemistry, Supplement, p. 208-216, 1994.	
CY	43	HOOSEIN, N.M., "Neuroendocrine and immune mediators in prostate cancer progression," Frontiers in Bioscience, p. D1274-1285, 1998.	
			:
			T
, 			

Examiner Date 1-21-03 Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.